K091589

510(K) SUMMARY

JUN 10 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: May 27, 2009

2. Name of the Device:

Microlife Digital Electronic Thermometer, Model MT16K1

3. Predicate Device Information:

Microlife Digital Electronic Thermometer, Model MT3001, K#851146.

4. Device Description:

This Digital Electronic Thermometer enables easy and highly accurate readings over the body temperature range and has been designed to provide maximum user-friendliness. The body temperature is measured by the thermistor and displayed as numbers on the LCD (liquid crystal display) through microprocessor of IC.

The basic principle of this thermometer is that change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of R-C oscillator circuit, Therefore, temperature can be given by measuring the frequency of oscillator.

For a given time period, by applying the R-C oscillator circuit, changes of temperature will correspond to changes of pulse number.

5. **Intended Use:** K091589

The Microlife Digital Electronic Thermometer MT16K1 is used for the intermittent measurement and monitoring of human body temperature, oral, rectal and under the arm. The device is for the audit and pediatric population.

6. **Comparison to Predicate Devices:**

The Microlife Digital Electronic Thermometer, Model MT16K1 is substantially equivalent to Microlife Digital Electronic Thermometer, Model MT3001, K#851146, which has the same intended use and is similar in design to the predicate device.

The Microlife Digital Electronic Thermometer MT16K1 and the predicate device are identical in the temperature measurements algorithm and fundamental scientific technology, differing mostly in probe tip and case material.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the ''FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers''.

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted in accordance with ASTM E1965-03 using the Microlife Digital Electronic Thermometer, Model MT16K1. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. **Conclusions:**

The Microlife Digital Electronic Thermometer, Model MT16K1 has the same intended use and similar technological characteristics as the Microlife Digital Electronic Thermometer, Model MT3001. Moreover, bench testing

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contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Digital Electronic Thermometer, Model MT16K1 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2009

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K091589
Trade/Device Name: Microlife Digital Electronic Thermometer, Model MT16K1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 29, 2009
Received: June 2, 2009

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

Indications for Use

510(k) Number (if known): K091589

Device Name: Microlife Digital Electronic Thermometer, Model MT16K1

Indications For Use:

The Microlife Digital Electronic Thermometer MT16K1 is used for the intermittent measurement and monitoring of human body temperature, oral, rectal and under the arm. The device is for the adult and pediatric population.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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